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| 10/081,457 | 02/21/2002 | Anne M. Pianca | 98P1021US08 | 3029 |

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

| EXAMINER | |
|---|---|
| EVANISKO, GEORGE ROBERT | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/08/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/081,457 | PIANCA ET AL. | |
| | Examiner | Art Unit | |
| | George R. Evanisko | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Newly submitted claims 22 and 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 22 and 23 are a combination of the originally presented subcombination claims. The inventions are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the electrode to be electrically coupled to one of the sides of the vessel wall or located on the helical bend, but located elsewhere on the lead, such as in the atrium. The subcombination has separate utility such as a lead without a lumen or stylet, but using a tether connected externally to the lead to shape/move the lead.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22 and 23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Response to Amendment*

As stated in the previous action--The applicant's billing records submitted on 6/8/06 ARE NOT PART OF A DECLARATION/AFFIDAVIT and therefore cannot be considered for

diligence. These documents are not in a declaration or affidavit since the applicant's arguments do not contain a statement by the declarant on the same document that warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true. Please see 37 CFR 1.68 and MPEP 715.04. In addition, it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). MPEP 716.01(c).

The examiner's position given in previous actions for both declarations (the valid declarations that were filed 12/12/05 and 8/30/04) is provided below.

The declaration under 37 CFR 1.132 filed 12/12/05 is insufficient to overcome the rejection of claims 1-20 based upon Chastain or the Chastain in view of Hsu references as set forth in the last Office action because: The declaration does not meet the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success. According to MPEP 716.03(a) "An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. Ex parte

Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988)." The declaration uses the language "[T]he commercial success of this lead is directly derived from the invention as claimed in the subject patent application" and the "Pacesetter's QuickSite left ventricular lead, which is covered by the claims of the subject application...has enjoyed considerable success" and that language does not establish the nexus. Although the lead has captured a 15-20% market share, this does not represent a majority of the market share and/or the commercial success may have been due to unclaimed features, low cost, heavy advertising, etc. In addition, it is unclear if the commercial success is related to the broad independent claims, the more narrow dependent claims, a specific claim limitation, or any claimed limitation since the particular claim limitations that have produced the commercial success have not been pointed out. Also, the declaration states that the marketing material for the lead stresses "superior handling and stability" and that these features have led to the commercial success, but the declaration does not state that the claimed features have led to marketing/commercial success. Finally, the evidence of long felt need is not persuasive. The claimed limitation which applicant has relied upon to show long felt need for a stable left side heart lead is "the S-shaped distal end". This limitation has been previously shown to be included in the lead of Chastain et al. Also, the margin of errors of the clinical trials and for the dislodgment rates have not been provided and without such data the stability could not be assessed.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

The 1.131. affidavits filed on 8/30/04 under 37 CFR 1.131 have been considered but are ineffective to overcome the Hsu et al (or Chastain) reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hsu reference to either a constructive reduction to practice or an actual reduction to practice. Exhibit B does not contain a date (See MPEP 715.07, "the actual dates of acts relied on to establish diligence must be provided") to show diligence. In addition, there are non-diligent time periods from: Exhibit B (dated "prior to March 19, 1998") to Exhibit C, dated June 27, 1997; from Exhibit C to Exhibit D of receiving a draft application on July 1, 1998--a period of over one year; Exhibit D To Exhibit E, dated October 23, 1998; and Exhibit E to the filing of the application, dated November 20, 1998.

Since no reduction to practice has been shown, the Examiner has concluded that the 1.131 declarations are used to show "conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice)" to show facts sufficient to establish prior invention of the claimed subject matter. The critical period in which diligence must be shown begins just prior to the effective date of the reference and ends with the filing date of the application (MPEP 715.07(a)). Exhibit B or any other exhibit does not contain a date to show diligence just prior to the effective date of the reference. In addition, there are numerous time periods between exhibits where diligence has not been shown. For example, between Exhibit C and Exhibit D a period of one year has elapsed (See MPEP 2138.06 regarding diligence required in preparing and filing patent application). In addition, after the draft was received by the Legal Department (Exhibit D) no diligence is shown for the three and a half month period until

receiving the revised draft. Finally, after the revised draft is received by the Legal Department, no diligence is shown for the period of approximately a month until the application was filed. (See MPEP 2138.06--"An applicant must account for the entire period during which diligence is required" and "A 2-day period lacking activity has been held to be fatal".)

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, 9, 12, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Chastain et al (5925073). Chastain discloses the claimed invention using an S shaped lead (figure 1) with peak to peak amplitude of 0.5-4.0 cm (column 2) and states it is used to make intermittent contact with the vessel wall (for claims 1 and 19). In addition, Chastain states that the S span is about 4-7 cm and shows in figure 1 the end of the span located 4-20 cm from the distal tip and therefore the distal electrode is anywhere from 0-13 cm away from the span and therefore within 50% of the peak to peak amplitude of the two bends. Finally, Chastain meets the claimed limitation of the electrode "coupled to...the vessel wall" since the electrode is used to deliver stimulation to the vessel wall and is coupled to the wall through the blood of the patient.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 11, 14, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chastain et al. Chastain shows in figures 1, 4, and 6 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees. In addition, Chastain states that a guidewire is used (column 3) and therefore would require a distal opening. In regards to claim 4, Chastain will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patient's wall (the "steerable canted end" is used in claim 2 when the stylet is partially withdrawn) and since Chastains electrode is oriented toward a wall since the electrode is oriented by the bends. Finally, for claim 18, Chastain states that a guidewire is used (column 3) and will meet the intended use recitations of

adapted to engage a stylet since the lead receives a guidewire and is therefore capable of receiving/engaging a similar size device, such as a stylet (the dimensions of the stylet have not been set forth.)

In the alternative, Chastain discloses the claimed invention except for the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and the tip electrode oriented toward the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and a tip electrode oriented toward the coronary wall since it was known in the art that heart leads having an anchor use: anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide good stability to prevent movement of the lead; a distal opening in the lead and the lead capable of engaging a stylet to allow the lead to be accurately placed in the heart using the guidewire and also allowing the lead to be further placed with a stylet; and the tip electrode oriented toward the coronary wall to provide physical contact with the wall for more effective stimulation.

Claims 1, 2, 5, 6, 9, 12, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain (5925073) in view of Hsu et al (6430449).

Chastain discloses the claimed invention using an S shaped lead (figure 1) with peak to peak amplitude of 0.5-4.0 cm (column 2) and states it is used to make intermittent contact with the vessel wall (for claims 1 and 19). In addition, Chastain states that the S span is about 4-7 cm

and shows in figure 1 the end of the span located 4-20 cm from the distal tip and therefore the distal electrode is anywhere from 0-13 cm away from the span and therefore within 50% of the peak to peak amplitude of the two bends. In the alternative, see the rejection below in view of Hsu for placing the electrode to contact the vessel wall (on the bend). But Chastain does not disclose a ring electrode coupled to one of the sides of the vessel wall (located on a bend--and the bends located 0.15-0.7 inches from each other--claim 8). Hsu teaches that it is known to locate a ring electrode so that it is coupled to one of the sides of the vessel wall (on the bend) to allow the electrode to be mechanically biased into physical contact with the coronary vein and therefore provide more effective stimulation and teaches to provide bends located 8-11 mm from each other (for claim 8) to stabilize the lead in the coronary vein. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with a ring electrode located to contact one of the on the bend and the bends located 8-11 mm from each other as taught by Hsu, since such a modification would provide a heart lead with a ring electrode located on the bend to allow the electrode to be mechanically biased into physical contact with the coronary vein and therefore provide more effective stimulation and would provide a heart lead with the bends located 8-11 mm from each other to stabilize the lead in the coronary vein.

Claims 4, 11, 14, and 18 are rejected under 35 U.S.C. 103(a) as obvious over Chastain et al. or over Chastain in view of Hsu ("the modified Chastain"). The modified Chastain shows in figures 1, 4, and 6 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees. In addition, Chastain

states that a guidewire is used (column 3) and therefore would require a distal opening. In regards to claim 4, Chastain will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patient's wall (the "steerable canted end" is used in claim 2 when the stylet is partially withdrawn) and since Chastains electrode is oriented toward a wall since the electrode is oriented by the bends. Finally, for claim 18, Chastain states that a guidewire is used (column 3) and will meet the intended use recitations of adapted to engage a stylet since the lead receives a guidewire and is therefore capable of receiving/engaging a similar size device, such as a stylet (the dimensions of the stylet have not been set forth.)

In the alternative, the modified Chastain discloses the claimed invention except for the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and the tip electrode oriented toward the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and a tip electrode oriented toward the coronary wall since it was known in the art that heart leads having an anchor use: anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide good stability to prevent movement of the lead; a distal opening in the lead and the lead capable of engaging a stylet to allow the lead to be accurately placed in the heart using the guidewire and also allowing the lead to be further placed with a stylet; and the tip electrode oriented toward the coronary wall to provide physical contact with the wall for more effective stimulation.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al or over the modified Chastain as applied to claims 6 and 1 above.

Chastain or the modified Chastain discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Chastain or the modified Chastain with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Chastain or the modified Chastain to anchor the lead in the coronary sinus and provide contact with the wall only along the humps.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain or the modified Chastain as applied to claims 2, 6, and 1 above. For claim 8, Hsu states that the bends are located 8-11 mm from each other. In addition, for claim 7, Chastain shows in figure 1 the bends being located 4-20 cm from the end and states the length of the bends are 4-7 cm long (column 2) and therefore provide a first bend located in the range of 0.15-0.7 inches from the distal end (in the alternative, see the rejection below).

Chastain or the modified Chastain discloses the claimed invention except for the stylet having a tapered portion, the first bend located in the range of 0.15-0.7 inches from the distal end, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

medical electrical lead as taught by Chastain or the modified Chastain with the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Chastain or the modified Chastain to include ePTFE as the textured region and the first bend being located 0.15-0.7 inches from the distal end, since applicant has not disclosed that ePTFE and the first bend being located 0.15-0.7 inches from the distal end provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Chastain (or the modified Chastain) in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Chastain or the modified Chastain to allow the lead to anchor in the coronary sinus and provide electrodes for electrical contact with the heart chambers.

***Response to Arguments***

Applicant's arguments filed 10/26/06 have been fully considered but they are not persuasive. As stated above and repeated below, the billing records filed 6/8/06 can not be used to show diligence because they are NOT IN DECLARATION OR AFFIDAVIT FORM. In

addition, the examiner understands about reasonable diligence required from an attorney when preparing an application, and that information will be considered when it is submitted in a valid declaration or affidavit. Also, the information submitted with the Applicant's arguments filed on 10/26/06 is not in affidavit/declaration form and will also NOT be considered for showing diligence. It is noted that diligence will need to be shown for the approximate one month time period from Exhibit E to the filing of the provisional application on November 20, 1998. Finally, the arguments in regards to Swoyer are not persuasive since Swoyer is not used in any of the rejections of the previous office action of 7/31/06.

The Examiners Response to Arguments from the detailed office action of 7/31/06 is repeated below.

Applicant's arguments filed 6/8/06 have been fully considered but they are not persuasive. The applicant argues that there is diligence and provides copies of documents purporting to show diligence. This is not persuasive since these documents are not in a declaration or affidavit and since the arguments do not contain a statement by the declarant on the same document that warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true. Please see 37 CFR 1.68 and MPEP 715.04.

In addition, it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). MPEP 716.01(c).

The argument that the declarations of August 30, 2004 establish conception and diligence before the effective date of the Hsu and Chastain references is not persuasive since the declarations of August 30, 2004 try to overcome only the Hsu et al reference used in the 103 rejections, and provide statements in the declaration that focus on the date of March 19, 1998 (the Hsu effective date). However, the 102 rejection above and previously presented relies on Chastain which has an earlier date than Hsu and therefore the declarations of August 30, 2004 will not be effective to overcome Chastain (unless the declarations are modified and meet the requirements, such as conception and diligence requirements).

The arguments that the declaration of December 8, 2005 provides proof of success is not persuasive. Please see the arguments at the beginning of this action regarding why that declaration is ineffective.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
12/27/6

GRE
December 27, 2006